PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: GRADON et al.

For: BREATHING ASSISTANCE APPARATUS

Serial No.: 10/785,646

Filed: February 24, 2004

Art Unit: 3743

Examiner: Mital B. Patel

Atty Docket No.: 1171/41687/139

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

December 29, 2005
Date

Tiffany E. Sexton
Tiffany E. Sexton

TRANSMITTAL OF CERTIFIED COPY
REGARDING CONVENTION CLAIM UNDER 35 U.S.C. §119

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In completion of Applicant's claim for priority under 35 U.S.C. §119 for United States Patent application, please find enclosed a true copy of the patent application as filed on 26 February 2003 with an application for Letters Patent number 524439.

It is believed that this completes Applicant's claim for priority and acknowledgment of receipt of this priority document is requested.

Respectfully submitted,

Date: December 29, 2005

By: _____

Raiford A. Blackstone, Reg. No. 25,156
Linda L. Palomar, Reg, No. 37,903
TREXLER, BUSHNELL, GIANGIORGI,
BLACKSTONE & MARR, LTD.
105 West Adams Street, 36th Floor
Chicago, Illinois 60603-6299
Tel: (312) 704-1890

Ministry of Economic Development
Manatū Ōhanga
Intellectual Property Office of New Zealand

CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 26 February 2003 with an application for Letters Patent number 524439 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 14 December 2005

CERTIFIED COPY OF PRIORITY DOCUMENT

Neville Harris
Commissioner of Patents, Trade Marks and Designs

COMMISSIONER OF PATENTS, TRADEMARKS & DESIGNS
NEW ZEALAND

330 High Street, Lower Hutt
PO Box 30687, Lower Hutt, New Zealand or DX SX 11129, Wellington
Freephone: 0508 4 IPONZ (0508 447 669), International callers dial: +64 3 962 2607, Fax: +64 4 560 1691, www.iponz.govt.nz

NEW ZEALAND

PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

Breathing Assistance Apparatus

We, FISHER & PAYKEL HEALTHCARE LIMITED a company duly incorporated under the laws of New Zealand of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

FIELD OF INVENTION

This invention relates to patient interfaces particularly though not solely for use in delivering CPAP therapy to patients suffering from obstructive sleep apnoea (OSA).

BACKGROUND OF THE INVENTION

In the art of respiration devices, there are well known variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the face such that gas may be provided at positive pressure within the mask for consumption by the user. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

One requisite of such respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear such a mask continuously for hours or perhaps even days. In such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

US Patent No. 5,243,971 and US Patent No. 6,112,746 are examples of prior art attempts to improve the mask system US Patent No. 5,570,689 and PCT publication No. WO 00/78384, and US Patent No. 6,119,693 are examples of attempts to improve the forehead rest.

SUMMARY OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface which goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

In a first aspect the present invention may be broadly said to consist in an interface for delivering pressurised gases to a user comprising

a housing configured to receive gases and deliver them to a user,

a forehead rest engaged with said housing and having a single area of contact with a user's forehead and including a bridge portion between a users forehead and said housing allowing a substantially unrestricted view for a users eyes.

Preferably said bridge member is adjustable or configurable in orientation with respect to said housing,

Preferably said bridge portion includes a pivoting engagement to said housing,

Preferably said bridge portion having substantially parallel side,

Preferably said forehead rest including attachment points for headgear, said attachment points lying in an approximately mid sagittal plane,

Preferably said interface is a mask,

Preferably said mask is a nasal mask.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

Figure 1 is a block diagram of a humidified continuous positive airway pressure (system) as might be used in conjunction with the present invention,

Figure 2 is an illustration of the nasal mask in use according to the preferred

embodiment of the present invention,

Figure 3 shows a perspective view of the mask with cushion,

Figure 4 is a cutaway view of the mask showing the cushion,

Figure 5 is a cutaway view of the periphery of the outer membrane,

Figure 6 is a cutaway view of the periphery of the mask body portion,

Figure 7 is a perspective view of the narrow forehead rest, and

Figure 8 shows the forehead rest in isolation,

Figure 9 shows the pivoting forehead rest with a locking mechanism,

Figure 10 shows the forehead rest with a spring loaded pivot,

Figure 11 shows the forehead rest with a malleable insert,

Figure 12 shows a section view of a forehead rest cushion,

Figure 13 is a section of a further forehead rest cushion,

Figure 14 is a perspective view of the mask showing the stop in a forward position,

Figure 15 is a cross section view of the mask showing the stop in a forward position,

Figure 16 is a perspective view of the mask showing the stop in a backward position,

Figure 17 is a perspective view of the mask showing the friction engagement,

Figure 18 is an alternate perspective view of the mask showing the friction engagement, and

Figure 19 is a cross section view of the friction engagement.

Figure 20 is a front view of the narrow forehead rest.

DETAILED DESCRIPTION

The present invention provides improvements in the delivery of CAP. therapy. In particular a patient interface is described which is quieter for the user to wear and reduces the side leakage as compared with the prior art. It will be appreciated that the patient interface as described in the preferred embodiment of the present invention can be used in respiratory care generally or with a ventilator but will now be described below with

reference to use in a humidified CAP. system. It will also be appreciated that the present invention can be applied to any form of patient interface including, but not limited to, nasal masks, oral masks and mouthpieces.

With reference to FIG. 1 a humidified Continuous Positive Airway Pressure (CAP.) system is shown in which a patient 1 is receiving humidified and pressurised gases through a patient interface 2 connected to a humidified gases transportation pathway or inspiratory conduit 3. It should be understood that delivery systems could also be VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. Inspiratory conduit 3 is connected to the outlet 4 of a humidification chamber 5 which contains a volume of water 6. Inspiratory conduit 3 may contain heating means or heater wires (not shown) which heat the walls of the conduit to reduce condensation of humidified gases within the conduit. Humidification chamber 6 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. Humidifier 8 is provided with control means or electronic controller 9 which may comprise a microprocessor based controller executing computer software commands stored in associated memory.

Controller 9 receives input from sources such as user input means or dial 10 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The controller may also receive input from other sources, for example temperature and/or flow velocity sensors 11 and 12 through connector 13 and heater plate temperature sensor 14. In response to the user set humidity or temperature value input via dial 10 and the other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5. As the volume of water 6 within humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 which enters the chamber through inlet 16. Exhaled gases from the patient's mouth are

passed directly to ambient surroundings in FIG. 1.

Blower 15 is provided with variable pressure regulating means or variable speed fan 21 which draws air or other gases through blower inlet 17. The speed of variable speed fan 21 is controlled by electronic controller 18 (or alternatively the function of controller 18 could carried out by controller 9) in response to inputs from controller 9 and a user set predetermined required value (preset value) of pressure or fan speed via dial 19.

Nasal Mask

According to a first embodiment of the present invention the patient interface is shown in Figure 2 as a nasal mask. The mask includes a hollow body 102 with an inlet 103 connected to the inspiratory conduit 3. The mask 2 is positioned around the nose of the user 1 with the headgear 108 secured around the back of the head of the patient 1. The restraining force from the headgear 108 on the hollow body 102 and the forehead rest 106 ensures enough compressive force on the mask cushion 104, to provide an effective seal against the patient's face.

The hollow body 102 is constructed of a relatively inflexible material for example, polycarbonate plastic. Such a material would provide the requisite rigidity as well as being transparent and a relatively good insulator. The expiratory gases can be expelled through a valve (not shown) in the mask, a further expiratory conduit (not shown), or any other such method as is known in the art.

Mask Cushion

Referring now to Figures 3 and 4 in particular, the mask cushion 1104 is provided around the periphery of the nasal mask 1102 to provide an effective seal onto the face of the user to prevent leakage. The mask cushion 1104 is shaped to approximately follow the contours of a patient's face. The mask cushion 104 will deform when pressure is applied by the headgear 1108 to adapt to the individual contours of any particular user. In particular, there is an indented section 1150 intended to fit over the bridge of the user's nose as well as a less indented section 1152 to seal around the section beneath the nose and above the upper lip.

In Figure 4 we see that the mask cushion 1104 is composed of an inner foam

cushion 1110 covered by an outer sealing sheath 1112. The inner cushion 1110 is constructed of a resilient material for example polyurethane foam, to distribute the pressure evenly along the seal around the user's face. The inner cushion 1110 is located around the outer periphery 1114 of the open face 1116 of the hollow body 1102. Similarly the outer sheath 1112 may be commonly attached at its base 1113 to the periphery 1114 and loosely covers over the top of the inner cushion 1110.

In the preferred embodiment shown in Figures 3-6 the bottom of the inner cushion 1110 fits into a generally triangular cavity 1154 in the hollow body 1102. The cavity 1154 is formed from a flange 1156 running mid-way around the interior of the hollow body.

The outer sheath 1112 fits in place over the cushion 1110, holding it in place. The sheath 1112 is secured by a snap-fit to the periphery 1114 of the hollow body. In Figures 5-6 the periphery 1114 is shown including an outer bead 1158. The sheath 1112 includes a matching bead 1159, whereby once stretched around the periphery, the two beads engage to hold the sheath in place.

Forehead Rest

In the preferred embodiment of the present invention the nasal mask 2102 includes a hinged forehead rest 106 (seen in Figures 2 and 8). The attachment of the forehead rest 106 to the hollow body 102 effectively allows the forehead rest 106 to move freely in proximity to the user but with no lateral movement.

In one form shown in Figure 8, pins 2130 are provided mounted on a base 2132 attached to the hollow body 102. These pins 2130 are co-axial within cylinders 2131 mounted on a bridge member 2136.

At the top end 2142 (around the user's forehead) of the bridge member 2136 harnessing slots 2138 are provided which allow straps from the headgear to be inserted to secure the mask to the headgear. For the users comfort one or more resilient cushions 2140 are provided underneath the top end 2142 of the bridge member 2136, which rest on the forehead of the user. The cushion 2140 might be constructed of silicon or any foam materials as is known in the art for providing cushioning.

In a further embodiment the forehead rest 106 described previously may include a

weakened section 2130 at its base 2132 which allows the joining member 2136 to pivot from the hollow body 102. The bridge member extends up to the forehead of the user. In a further alternative the mask may include a vertical upwardly extending inlet. In this case the member 2136 is hinged at its base 2132 to either side of the inlet passage. Again the member would then extend to the forehead.

In a still further embodiment shown in Figure 9 the forehead rest 106 is shown with the pivoting action which can be locked in a single position. As before the bridge member 136 pivots by virtue of pins from the hollow body 102 co-operating with cylinders 131 on the bridge member 136. The locking action is provided by an engaging clip 200 which is attached through an aperture at the base of the bridge member 136. The lock and clip 200 has a number of ribs which engage with at least two ribs on the interior of the aperture which allows it to lock and place it in at least an upper position and a lower position. In the upper position the locking clip 200 is clear of the hallow body 102 and allows the bridge member 136 to pivot freely. In the lower position the locking pin 200 engages with a cavity on the surface of the said hollow body 102 which locks said bridge member 136 at a predetermined angular position with respect to said hollow body 102. In the preferred embodiment this position provides the maximum off set of the upper section of the mask from the bridge of the patient's nose.

In another embodiment shown in Figure 10 the forehead rest 106 is shown with a spring loaded attachment 202 to the hollow body 102. The force provided by the spring 202 is adjusted to give an optimum pressure on the bridge of the uses nose. This ensures adequate sealing around the nose and prevents any excess pressure causing irritation. The spring comprises a spirally wound spring attached at one end to the hollow body 102 and at the other to the base of the bridge member 136. The bridge member 136 is also independently individually mounted to the hollow body 102 as previously described. The spring 202 is biased to provide a clockwise moment as shown in Figure 10.

In a further embodiment shown in Figure 11 the forehead rest 106 is shown including a malleable insert 204. The preferred embodiment the malleable insert 204 comprises a metal strip joining the hollow body 102 to the forehead rest 106. The metal

can be chosen from anyone of a number of metals known in the art to provide enough malleability to be bend to a particular angle and enough stiffness to retain the angle once installed on the patient. The malleable member 204 maybe connected to the hollow body 102 by mounting 206.

In a still further embodiment shown in Figures 14 to 16 the present invention is illustrated similarly to the forehead rests previously described, with a pivoting bridge member 300 and an adjustable pivot stop 302. The bridge member 300 is attached to and pivots about pins 304 extending from in the side of the upwardly extending inlet conduit 306 of the mask 305. The pins 304 engage with matching apertures 308 in the bridge member 300.

The pivot stop 302 may be adjusted into a number of predetermined positions whereby the angle to which the forehead rest member 300 can freely pivot is restricted. Accordingly the pivot stop 302 requires an adjustable engagement with the bridge member 300. Preferably the engagement is provided with a locking clip 310 which engages with any one of a number of mating depressions or protrusions 312 in the bridge member 300. Alternatively the engagement could be provided by for example a friction engagement including some tensioned member (not shown) frictionally engaging the bridge member 300. The tensioned member could be releasable to allow movement and engagable to fix the position.

For example as shown in Figure 14 with the pivot stop 302 in a forward position the angle (Figure 15, 314) of movement is restricted to very little or a small range of movement with the forward rest cushion 314 positioned at the maximum distance away 315 from the axis of the inlet conduit 306. As shown in Figure 16 with the pivot stop 302 in a backward position the angle 314 of movement is much less restricted such that the cushion 316 may be pivoted to a position 318 much more proximate the inlet conduit 306.

In a still further embodiment shown in Figures 17 to 19 the bridge member 430 according to the present invention is shown including a friction engagement 432 with the mask body 434. In this embodiment the mask body 434 is shown with an elbow connector 436 connected to the inlet conduit 438. An adjustment knob 440 provided on the side of

the bridge member 432 allows adjustment. With the knob 440 in a loosened position the bridge member 430 may be pivoted to any desired angle with respect to the mask body 434. Once in the desired position the knob 440 may be configured to a tightened position whereby the angle of the bridge member 430 relative to the mask body 434 is substantially fixed by virtue of the friction engagement in the interlocking parts.

In more detail shown in Figure 19 the knob 440 includes a helical thread engaging with a reciprocal helical thread 441 on pin 442 running transversely through the bridge member 430. The pin also runs through apertures in flanges 444 extending up from the mask body 434 and an internal flanges from 446. In this fashion the flanges 444 and 446 may frictionally engage (optionally also with the inner surfaces of the bridge member 430) once the knob 440 is in a tightened position. Adjustment may either be allowed in a finite number of predetermined positions or may be completely variable.

In Figures 7 and 20, a further embodiment of a forehead support of the present invention is illustrated. In this embodiment a narrow forehead rest 500 is included to minimise the profile and frontal appearance of the mask.

The bridge member 532 is narrow with parallel sides. The adjustment knob 550 on the side of the opposite side of the friction member 520 allows adjustment. When the adjustment knob 550 is a loosened position the bridge member 530 can be adjusted to any desired angle relative to the mask body 510. Similarly to previous embodiments. It may also be fixed or include a malleable inset. The single cushions 560 attaches to the apex, 546 of the bridge member. Headgear attaches through slots 540, 542 which extend away from the forehead in an approximately mid sagittal plane.

The forehead rest is most preferably thermoplastic polycarbonate or similar, and manufactured by injection moulded. The advantage is that the forehead support is small and streamlined as the headgear attachment points are placed above the main forehead support structure, rather than sticking out the side, which is the traditional approach. A mask that looks smaller is less intrusive.

Forehead Rest Cushion

Referring now to Figure 12 one embodiment of the forehead rest cushion 140 is

illustrated. The cushion 140 in cross section generally includes a first convex member 210 and a second inner convex member 212 both of which are attached at each end to a straight base member 214. The inner convex member 212 is a substantially flatter convex shape than the first convex member 210. In this fashion when the cushion 120 comes into contact with the users face the first convex member 210 deforms as more pressure is applied to the cushion towards the face. This comprises of the first mode of deformation. Once the first convex member 210 deforms enough to contact the second convex member a second mode of deformation occurs. As will be appreciated as the first convex member is less flat than the second convex member 212 the first mode requires less force. Once in the second mode of deformation extra force is required to deform both the first convex member 210 and the second convex member 212 as well as the fact that a flatter convex shape requires more force to deform. This configuration described above results in more even deformation force across the load bearing surface of the cushion 216 and also results in a more distributed force of cushioning when the cushion 120 is deformed.

In a further embodiment shown in Figure 13 the forehead rest cushion 120 is shown with a first convex member 220 attached at either end to a straight base member 222. A second convex member 224 is inverted with respect the first convex member 220 and is attached at either end two points on the 226, 228 on the first convex member 220. The second convex member is lower in overall height than the first convex member 220 such that a first mode of deformation occurs when the first convex member 220 is deformed. A second mode of deformation occurs when the second convex member 224 contacts the base member 222. The first convex member 220 and the second convex member 224 deform simultaneously. The forces across the load bearing surface 230 are further distributed by virtue of a generally quadrilateral member 232 including as one side the base member 222 which attaches over the first convex member 220 approximately at its ends and at its load bearing point 234. The quadrilateral member 232 provides additional stiffness and reduces lateral deformation.

In either embodiment the base includes a T-piece 240 which engages with a slot

2138 in the forehead rest 106.

DATED THIS 26 DAY OF February 2003
AJ PARK
PER
AGENTS FOR THE APPLICANT

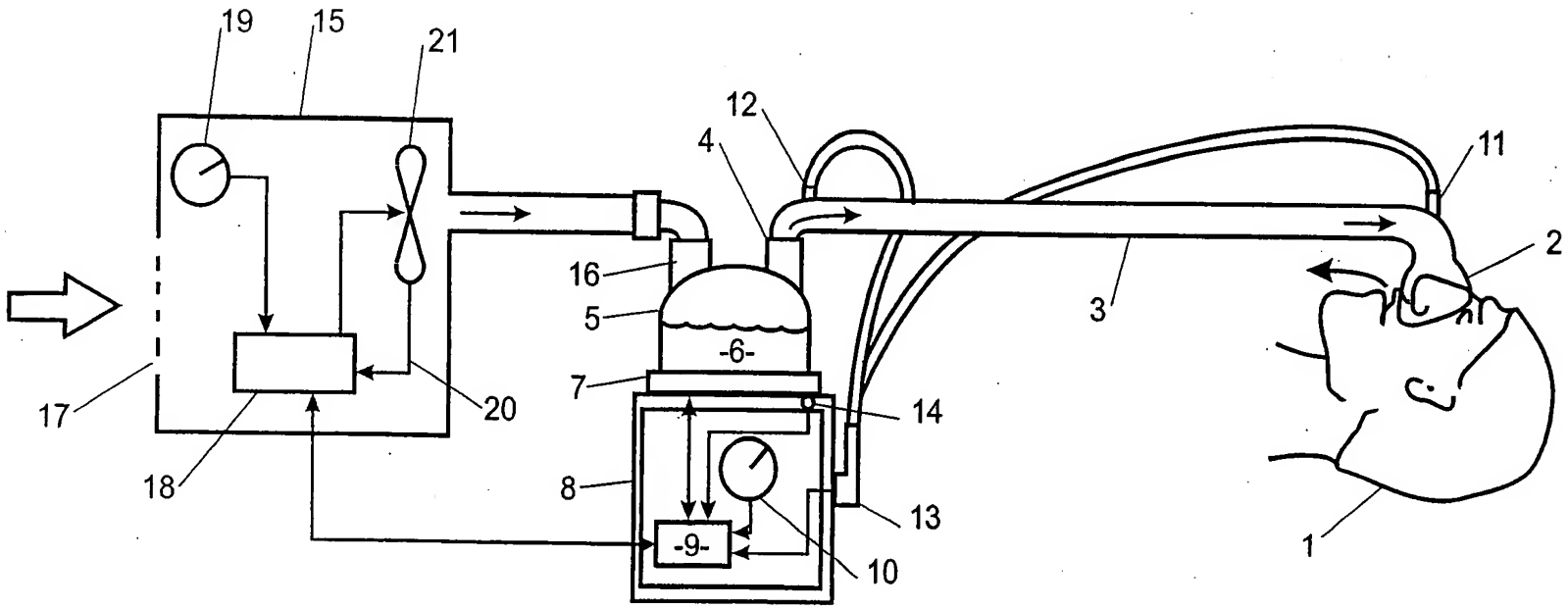

FIGURE 1

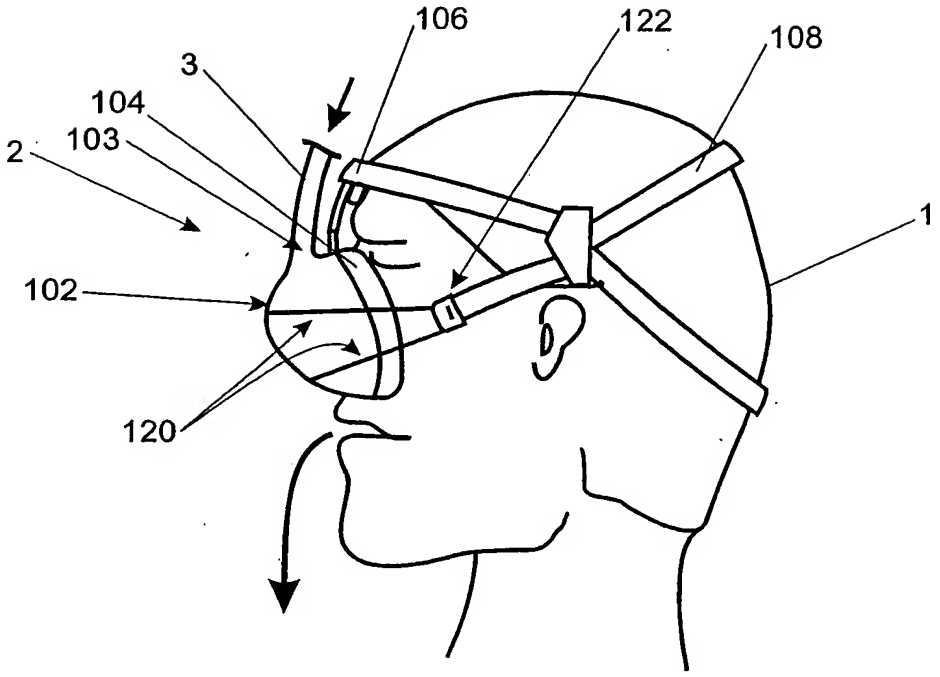

FIGURE 2

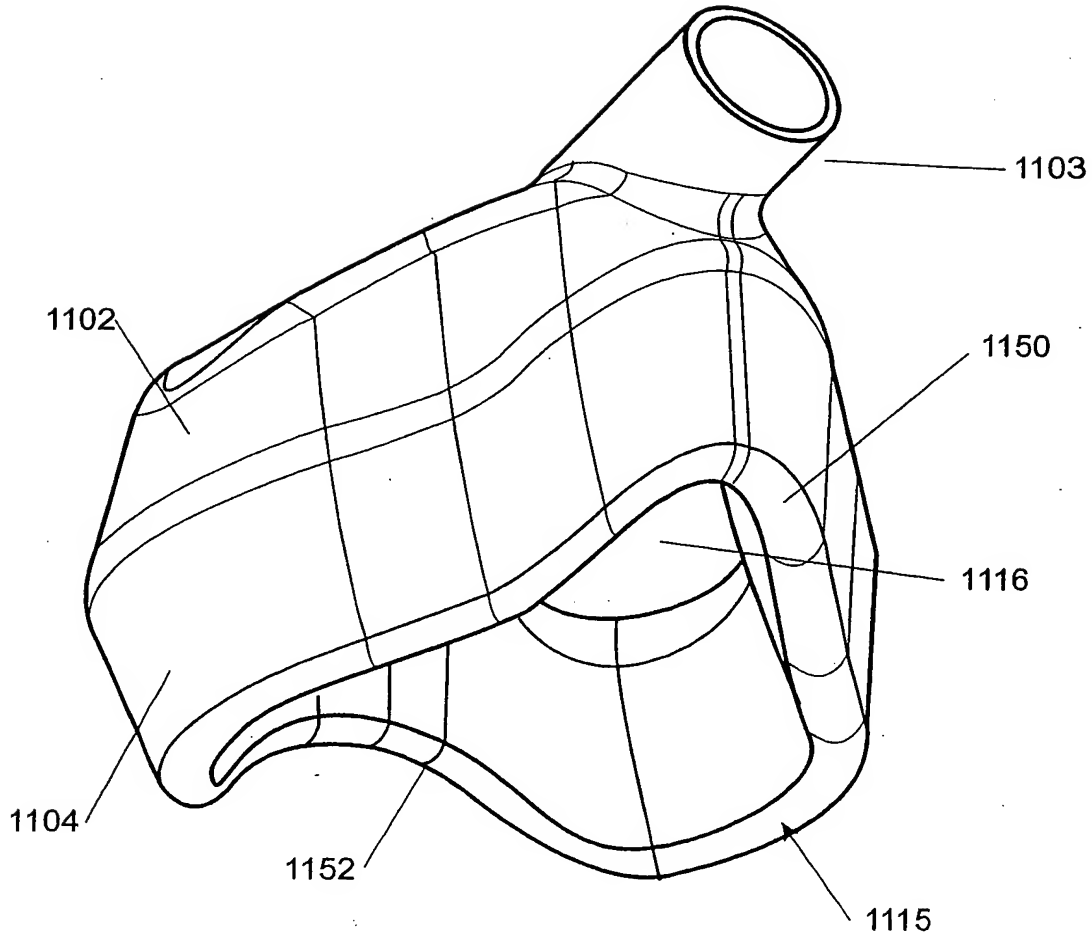

FIGURE 3

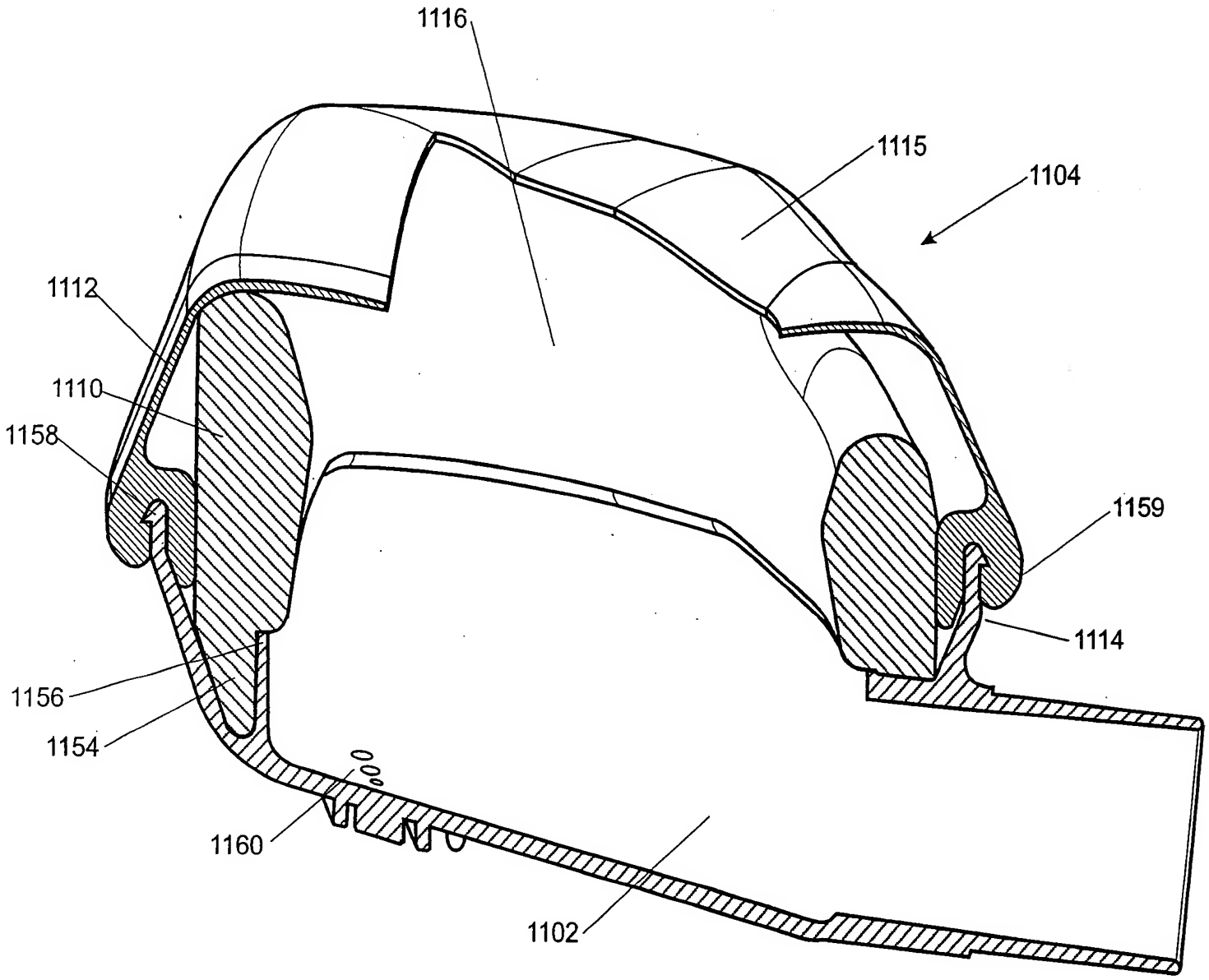

FIGURE 4

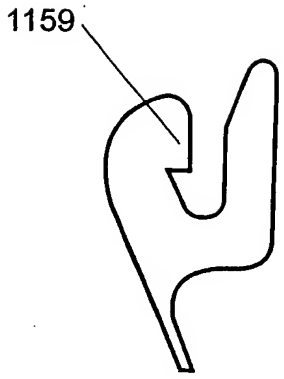

FIGURE 5

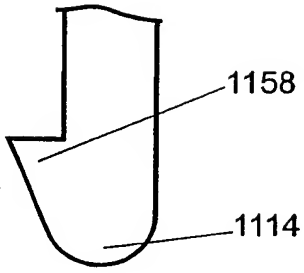

FIGURE 6

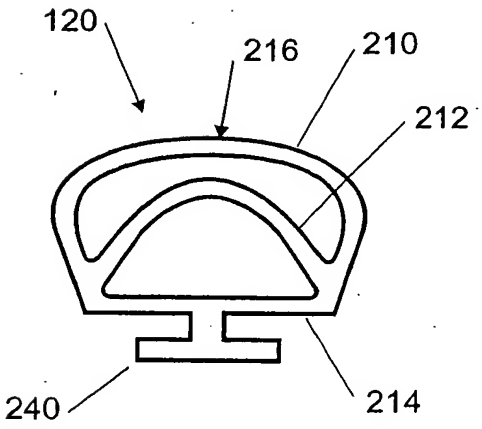

FIGURE 12

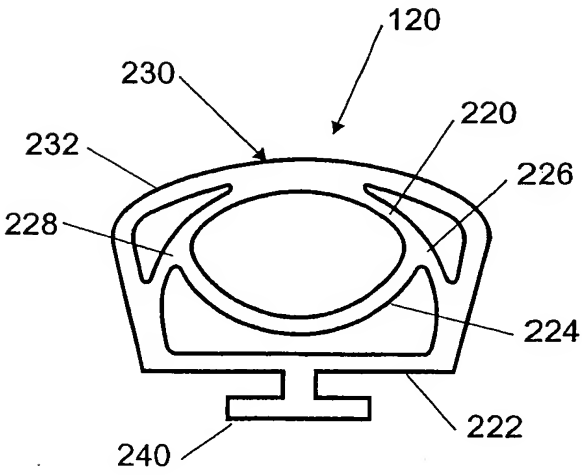

FIGURE 13

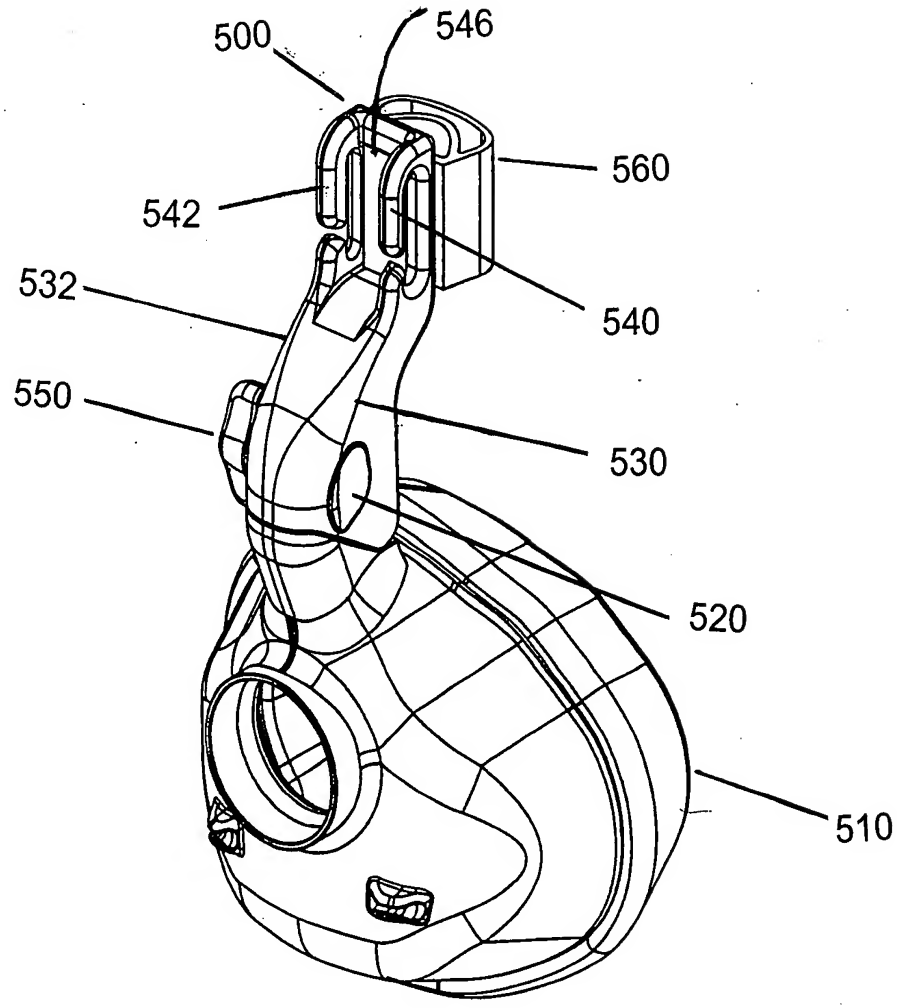

Figure 7

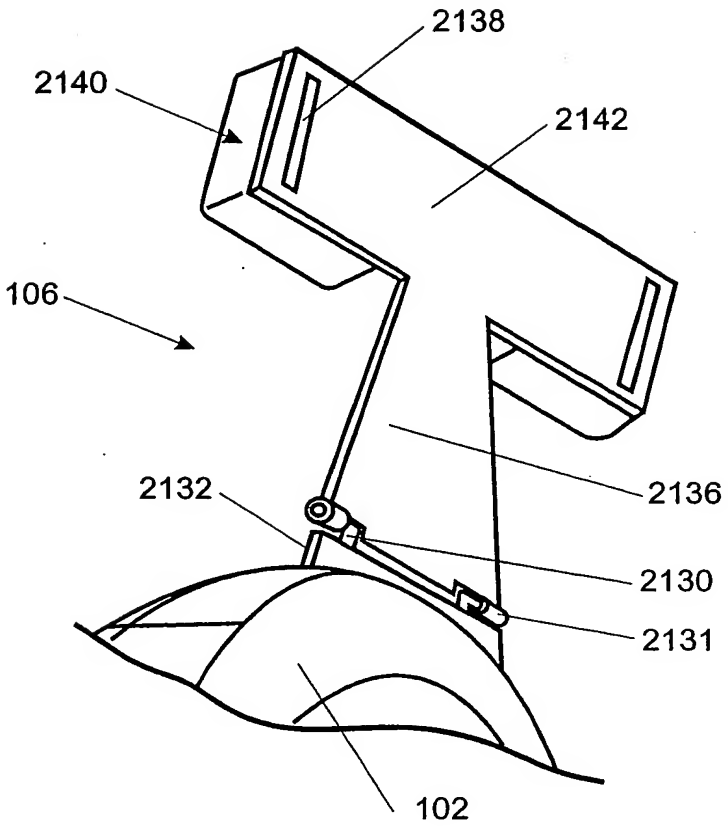

FIGURE 8

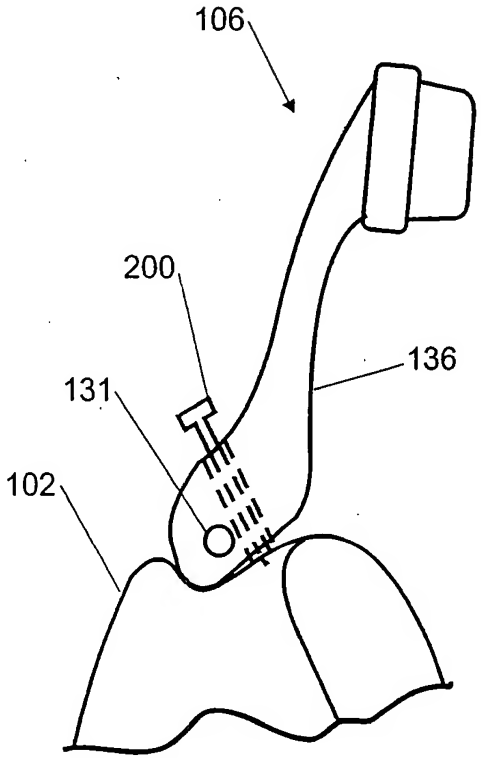

FIGURE 9

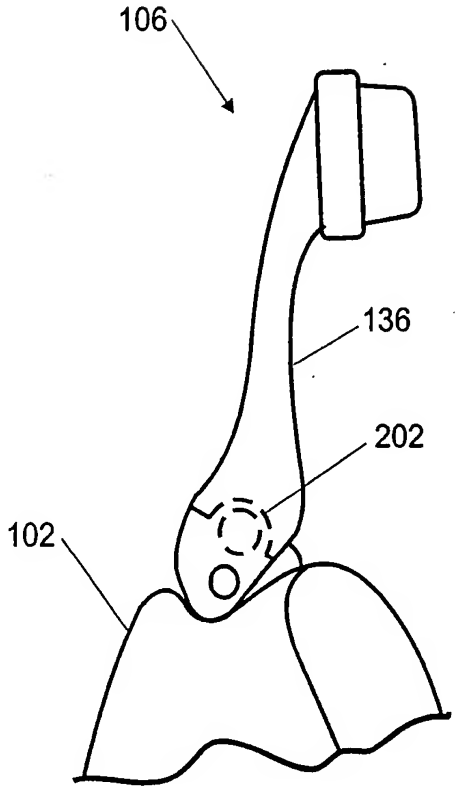

FIGURE 10

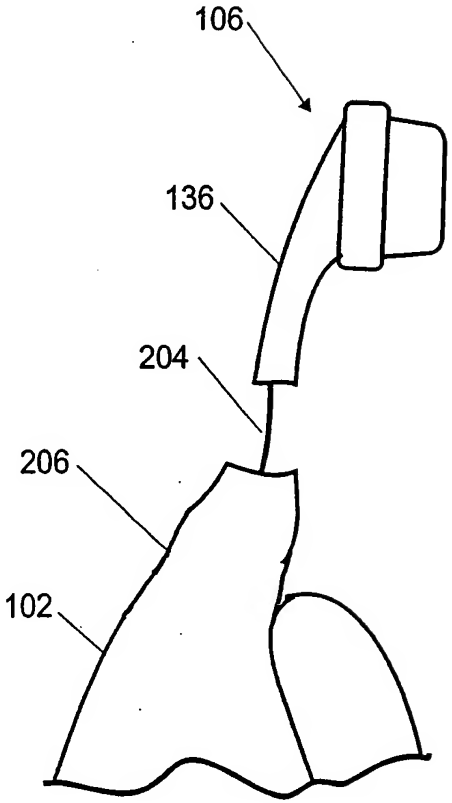

FIGURE 11

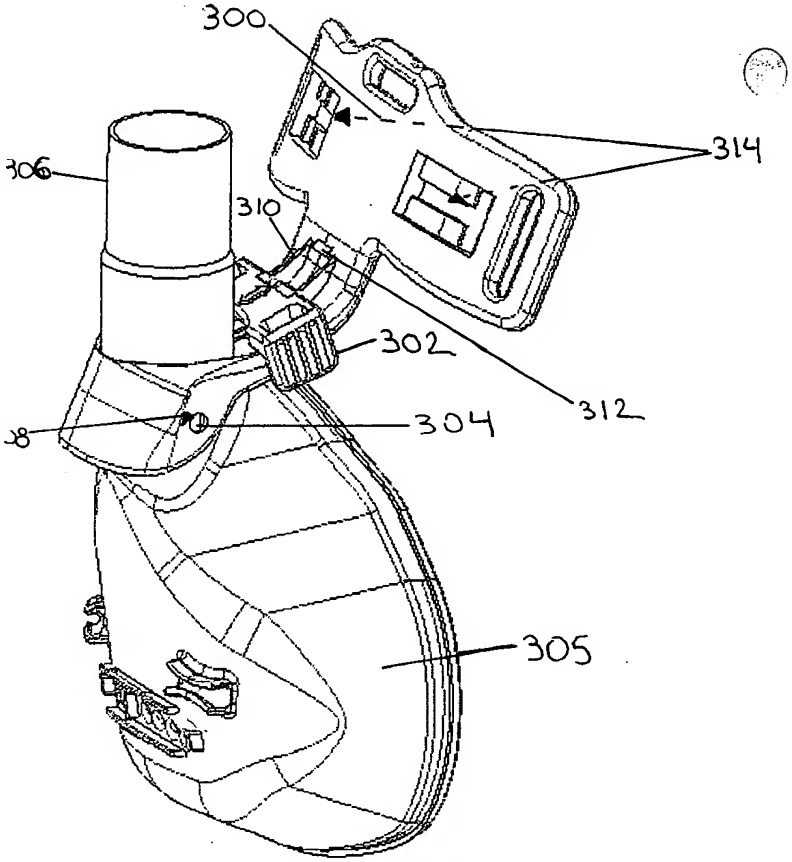

FIGURE 14

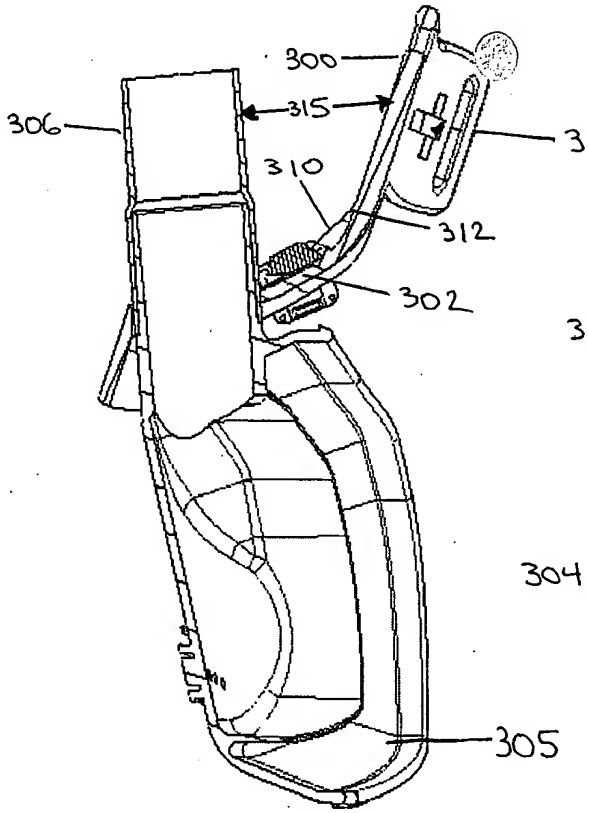

FIGURE 15

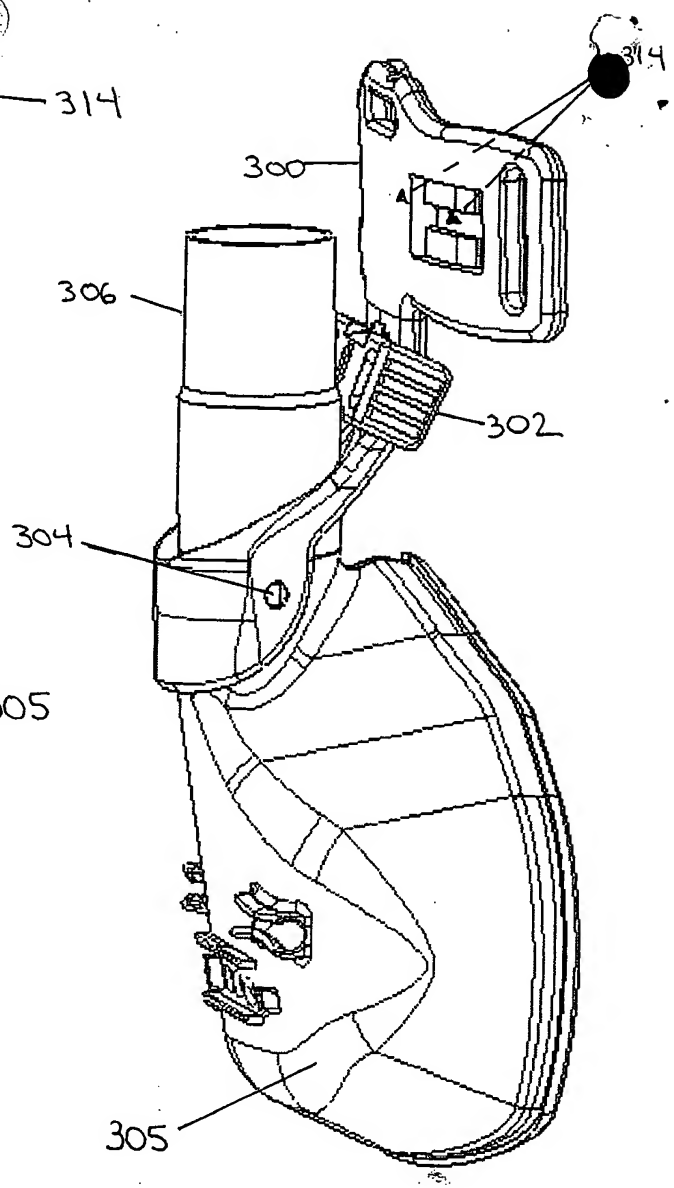

FIGURE 16

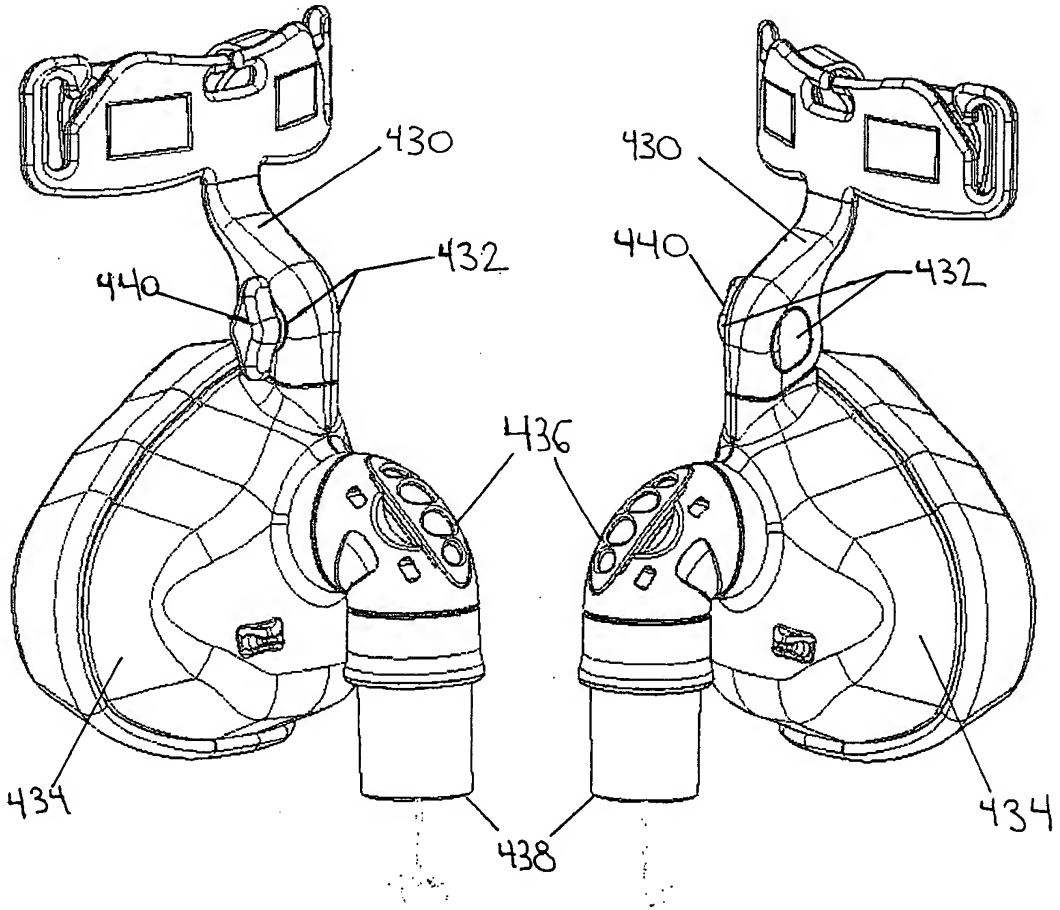

FIGURE 17

FIGURE 18

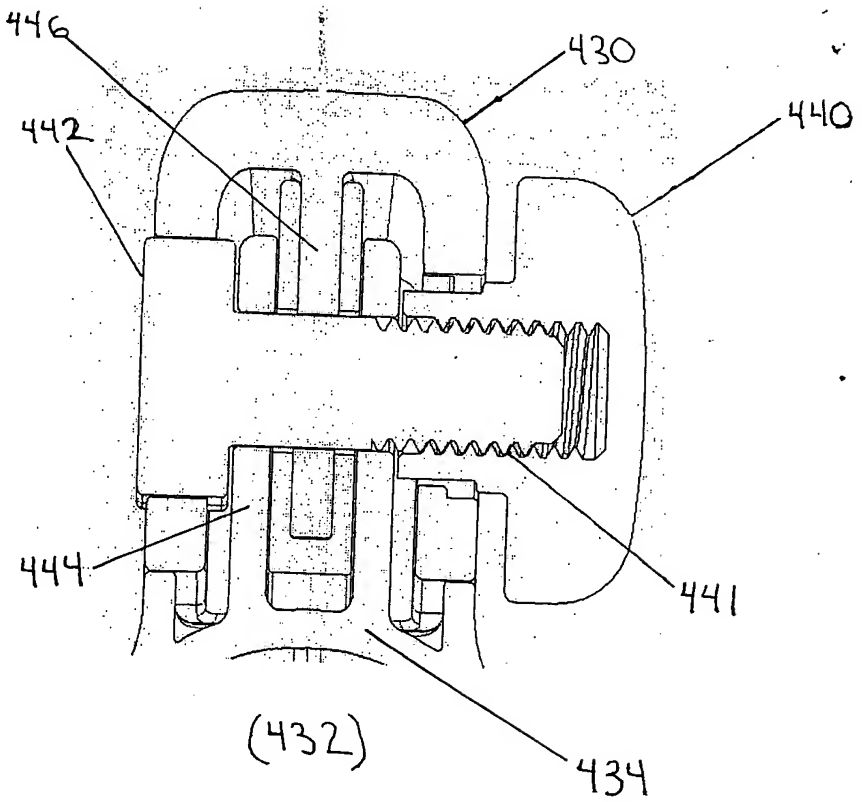

FIGURE 19

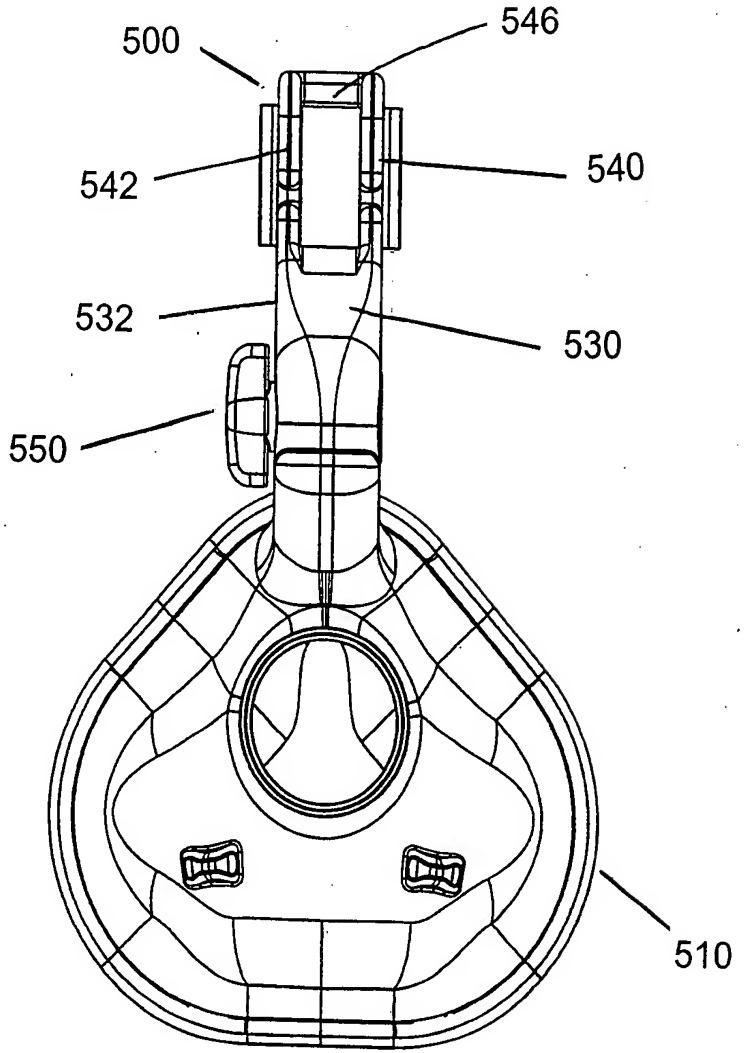

Figure 20